UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456
THIS DOCUMENT RELATES TO:	Civil Action No. 01-12257-PBS
United States of America, ex rel. Ven-a-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., CIVIL ACTION NO. 06–CV-11337-PBS	Subcategory Docket: 06-CV-11337-PBS Hon. Patti B. Saris
United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Dey, Inc., et al., CIVIL ACTION NO. 05-11084-PBS	
United States of America ex rel. Ven-a-Care of the Florida Keys, Inc., et al. v. Boehringer Ingelheim Corporation, Inc., et al., CIVIL ACTION NO. 07-10248-PBS	

UNITED STATES' COMMON REPLY MEMORANDUM OF LAW IN SUPPORT OF CROSS-MOTIONS FOR PARTIAL SUMMARY JUDGMENT AND SUR-REPLY IN OPPOSITION TO THE DEFENDANTS' MOTIONS FOR SUMMARY JUDGMENT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

FEDERAL CASES

STATUTES

Fraud Enforcement and Recovery Act of 2009:

RULES & REGULATIONS

INTRODUCTION

In the midst of the deluge of papers filed in connection with summary judgment motions, it is important to remember some basic facts that defendants would prefer the Court to forget: the Medicare and Medicaid programs serve the most vulnerable citizens in our society -- the aged and the poor. The more money that is siphoned from these programs due to fraud, the more frayed the safety net becomes for people who need medical care but cannot afford it. Defendants have treated these programs and, by extension, the program beneficiaries, as pawns in their pursuit of more sales and greater profits.

Summary judgment turns on two core issues. First, did defendants have the right to report *any* number they wished as their average wholesale price ("AWP")? Defendants contend that because AWP was not "defined," they were free to report any price they chose - whether or not it had any basis in reality. Following this logic, there could be no such thing as a "false" AWP under the False Claims Act (FCA). Although the Court already rejected this interpretation in the context of its class action ruling in the MDL, defendants urge the Court to reconsider based on discovery taken in these three cases. Defendants essentially claim that AWP does not mean what it says -- at least with respect to multi-source drugs where the spreads created by defendants' pricing exceed the typical brand spreads.

The second key issue is whether, as defendants contend, the federal government impliedly "approved" of defendants' false price reporting by implementing a policy of deliberately overpaying, by an unknown amount, on the ingredient cost of an unknown number of drugs, in order to "cross-subsidize" dispensing fees that were supposedly uniformly inadequate. Despite public regulatory efforts by federal and state governments to rein in drug costs through federal upper limit ("FUL") and maximum allowable cost ("MAC") programs,

defendants argue that such an official policy existed and constituted approval of both their AWPs and the resulting claims for reimbursement based on those AWPs.

As detailed below, the Court should reject both premises. Pharmaceutical manufacturers were not handed the keys to the reimbursement kingdom when AWP was inserted in federal regulations in 1991. It is nonsense to suggest that the United States ceded to drug makers the authority to decide how much "extra" profit pharmacies and doctors should make on prescriptions, or how much additional money Medicare patients should have to shell out in co-payments for drugs. Nor did the United States Department of Health and Human Services (HHS) and state governments deliberately sanction the reporting of inflated prices to "cross-subsidize" purported shortfalls in dispensing fees.

Having raised the government knowledge/government policy argument in multiple defenses, defendants had the burden of demonstrating such a policy existed. They have not done so. Accordingly, the United States is entitled to summary judgment on such defenses. Based on clear and compelling evidence, the United States is also entitled to summary judgment on the issues of defendants' role in the submission of the false claims, the materiality of defendants' false statements, and defendants' scienter. Finally, defendants have failed to establish grounds for summary judgment as to either unjust enrichment or damages.

ARGUMENT

I. DEFENDANTS HAVE FAILED TO MEET THEIR BURDEN OF ESTABLISHING APPROVAL BY THE GOVERNMENT

The First Circuit's decision in *United States v. Lachman*, 387 F.3d 42, 54-55 (1st Cir. 2004), provides a framework for wading through the reams of materials submitted by defendants. At bottom, defendants contend that HHS interpreted its regulations to mean that (1) defendants

could report whatever they wished as AWP, and (2) the agency could (and did) approve the reporting of AWPs untethered to actual prices for an unknown number of drugs in order to make up for supposed underpayments on dispensing fees. Under *Lachman*, in order to prove either interpretation, defendants must point to formal, public agency pronouncements. After years of discovery of both federal and state governments, defendants have failed to establish either point.

Lachman involved a defendant seeking to avoid prosecution by arguing, as defendants do here, that based on the testimony of current or former government employees, a government regulation meant something other than what it said. Defendant contended that the Department of Commerce's failure to define the term "specially designed" in an export control regulation meant (1) the regulation could not be used as the basis for a criminal prosecution, and (2) the court must adopt an interpretation based on the testimony of former and current government employees.

The *Lachman* court rejected both propositions. The court first looked to the Supreme Court's emphasis on the plain meaning rule in both statutory and regulatory interpretation. After finding that dictionary definitions presented a choice of broader or narrower interpretations, the First Circuit looked to the statute to ascertain its overarching purpose and adopted "the definition most consistent with the statute's purpose." 387 F.3d at 51. The *Lachman* court specifically rejected any reliance on current and former agency employee affidavits on two separate grounds. First, the court noted that it would "look to agency interpretations only when the statute or regulation remains ambiguous after we have employed the traditional tools of construction." *Id.* at 54. Second, the court held that even under those circumstances, "agency interpretations are only relevant if they are reflected in public documents. . . . the same requirements [as for

interpreting statutes] of public accessibility and formality are applicable in the context of agency interpretations of regulations." *Id*. When confronted with evidence almost identical in type to what defendants present here, the First Circuit held, "The non-public or informal understandings of agency officials concerning the meaning of a regulation are thus not relevant. The affidavits here of former and present agency officials as to the agency's non-public understanding of the regulation do not remotely satisfy the requirements of formal and public accessibility." *Id*.

A. AWP Does Not Stand for "Anything a Pharmaceutical Manufacturer Wants to Publish"

Pharmaceutical manufacturers are fond of quoting that AWP "stands for ain't what's paid." What they really mean when invoking that phrase, however, is that AWP stands for anything a manufacturer wants to publish. Defendants boldly contend that they were free to report any price they wished – even knowing that the price would be used to calculate Medicare and Medicaid reimbursement. Defendants rely on highly selective sound bites from former federal and state employees to argue that their interpretation was also held by the programs themselves and therefore should be adopted by this Court.

1. The Evidence Put Forward by Defendants Is Irrelevant Under *Lachman* and Factually Misleading

The First Circuit has made clear that testimony of former or even current government employees is not relevant evidence when interpreting a statute or regulation. Even so, defendants here rely heavily on testimony by former and current employees of CMS and state Medicaid agencies who, when asked essentially, "what does AWP mean to you," often replied by describing what reported AWPs *became* in the hands of defendants. That witnesses testified to learning, over time, that published AWPs grew more distant from actual transaction prices is

not surprising in light of both manufacturers' conduct and the OIG's efforts in this area. Such statements do not, however, conflict with the Court's ruling as to the meaning of AWP.

Moreover, the testimony cited by defendants is factually misleading to the extent it purports to portray a point of view within either federal or state governments that AWP as used in statute or regulation was meant to be (and accepted as) meaningless. On this point, defendants ignore the testimony of several federal officials, including Donald Thompson, a current CMS career employee and the government's Rule 30(b)(6) representative, and two of the most senior career CMS officials deposed in this case, Thomas Gustafson and Kathleen Buto. Testimony by all three reflects an understanding that AWP was not meant to be an anything-goes number.

When asked his understanding of AWP, for example, Mr. Thompson testified that: "From a regulatory perspective, if you look at the rulemaking documents -- so if you examined the 1991 rulemaking cycle, and then also the 1998 rulemaking cycle, *the term AWP has a plain language meaning*." (3/28/08 Thompson Dep. at 82:13-17, Henderson Reply Ex. 93, emphasis supplied.) When asked his opinion whether AWP in the 1991 regulations referred to an empirical average of wholesale prices, Mr. Thompson testified, "I guess what I'm saying is that in the context of the rulemaking documents, *the word average means average, the word wholesale means wholesale and the word price means price*. And what I'm trying to think through is does my answer change when I think about the list AWP in the compendia. And I think the answer to that question is no." (3/28/08 Thompson Dep. at 83:1-8, Henderson Reply Ex. 93, emphasis supplied.)

Mr. Gustafson, a longstanding career CMS policy official who now works in the private sector, testified similarly regarding his understanding of AWP as used in federal regulations and

the Balanced Budget Act of 1997 (BBA), Pub. L. 105-33, 111 Stat. 462-463 (1997), noting that the compendia prices were a source of information for AWP as used in the BBA.[1]

> Q. How did the agency interpret the statute in this particular instance?
>
> A. I think it's well-known. *We used average wholesale price in the Red Book as a reflection of average wholesale price as called for by the statute.*

(12/17/07 Gustafson Dep. at 258:3-7, Henderson Reply Ex. 94, emphasis supplied.)

When deposed in this case, Ms. Buto had been a vice-president with Johnson & Johnson since 2001. Prior to that, Ms. Buto began her career with HHS in 1977, when she joined its predecessor agency. She held a variety of high-ranking career policy positions with HCFA starting in 1982, dealing with both the Medicare and Medicaid programs, continuing until she left the agency in 2000.[2] When she was asked about the pitfalls of relying on reported prices as a basis for reimbursement, she testified as follows:

> A. We were aware that based on some IG surveys that we believed that those were not reliable reflections of what we should actually be paying. So whether you'd call that a deficiency or not, we felt they were just not a reliable basis.
>
> Q. Now, when you say not a reliable basis, what do you mean by that?
>
> A. They seemed to -- if we continued paying based on average wholesale price they

---

[1]Mr Gustafson held the following positions at CMS.: 2003–2007 – Deputy Director in Center for Medicare Management, CMS; 1998- 2003 Director of Hospital and Ambulatory Policy Group, CMS; 1997–1998 – Deputy Director of Office of Strategic Planning, HCFA; 1996–1997 – Office of Research and Demonstrations, HCFA; 1990–1996 – Deputy Director, Office of Legislation and Policy, HCFA; 1988-1990 – Director of Office of Policy Analysis, Office of Legislation and Policy, HCFA; 1985 – 1988 – Director of Division of Medicaid and Long-term Care, Office of Policy Analysis, Office of Legislation and Policy, HCFA. (9/28/07 Gustafson Dep. at 33:7 – 49:5, Henderson Reply Ex. 95)

[2]Ms. Buto held the following positions: 2000-2001 – Senior Health Advisor Congressional Budget Office; 1997–2000 – Deputy Director, Center for Health Plans and Providers, HCFA; 1993-1997 – Associate Administrator for Policy, HCFA; 1989-1993 – Director of Bureau of Policy Development, HCFA; 1985-1989 – Deputy Director, Bureau of Policy Development; 1983-1985 – Director of Office of Executive Operations, HCFA; 1982-1983 – Deputy Director of Office of Executive Operations, HCFA. (9/12/07 Buto Dep. at 45:4-63:7, Henderson Reply Ex. 21)

> seemed to be inflated. And the inspector general surveys seemed to indicate that it was in the neighborhood of 15 or 16 percent too high. So that's what I mean by not a good basis. *Our premise was always what should we be fairly paying, not -- and we were always looking for ways to be more accurate.*[3]

(9/12/07 Buto Dep. at 128:10-129:4, Henderson Reply Ex. 21, emphasis supplied.)

Defendants also conveniently ignore testimony regarding the significant problems caused for states by false AWPs, testimony that contradicts any notion that state personnel were indifferent to, much less approved of, defendants' conduct. The witness for Illinois Medicaid, for example, one of the largest Medicaid programs in the country, explained how states had to adopt increasingly complicated reimbursement formulas to address the issues presented by defendants' conduct. When asked if Illinois had adopted a definition of estimated acquisition cost using the survey discounts set forth in an OIG report, James Parker, Deputy Medicaid Administrator, first noted that surveys reflect aggregate numbers, and that "[t]hey are not saying that every generic is available at AWP minus 45 or 85 or 60 . . ., and in fact, evidence would suggest they're not." He went on to testify:

> *That's the problem caused by inaccurate AWPs, you don't know where they are with relation to reality on a drug-by-drug basis, and we have to reimburse on a drug-by-drug basis.* Were we to use a formula that simply said 'AWP -85%,' we would be grossly underpaying costs on many generics, particularly newer generics. Hence, the need to have a multitiered process that uses a formula based on AWP or a Federal Upper Limit or a State MAC.

(11/18/08 Parker Dep. 241:9-15; 241:17-22, Henderson Reply Ex. 33, emphasis supplied.)

---

[3] Ms. Buto also flatly contradicts the notion that the agency approved inflated AWPs:

Q. You knew by using average wholesale price in reimbursement methodologies that you were not getting to a real acquisition cost; is that right?

A. We strongly suspected we were not, but we did not have the data to prove that we were not, which is why -- in my time there were numerous attempts to try to figure out how to get better data. The OIG was one source of that data.

(9/12/07 Buto Dep. at 143:21-144:8, Henderson Reply Ex. 21.)

Officials for state after state confirmed that they relied on AWPs to effect their program's goal of estimating acquisition costs for thousands of products. (*See, e.g.*, 10/21/08 Weeks Dep. 133:13-136:10, Henderson Reply Ex. 34 (testifying that North Carolina relied on AWPs as having a link to real prices and had no way of knowing which AWPs might be inflated far above market prices)). Likewise, the representative for the state of North Dakota was directly asked whether there were policy goals served by inflated AWPs, and testified, "We had no such policy goal to where the lack of specificity of AWP or nonrelationship to the acquisition cost benefitted us." (12/12/08 Joyce Dep. 274:3-5, Henderson Reply Ex. 9.) At the end of the day, defendants' conduct benefitted themselves, while it undercut the entire regulatory system the federal government and states were trying to implement. Far from approving, states were frustrated and dismayed. Medicaid witnesses testified to the need for accurate pricing data, observing that AWP was the best available data, *see, e.g.*, Rhode Island, 12/3/2008 Young Dep. 238:11-12, Henderson Reply Ex. 41, or as one Medicaid agency 30(b)(6) witness put it: "it is a sad commentary on the profession that we have no data element that we can reliably use for ingredient costs. . . ." (12/10/2008 Denemark Dep. at 486:8-11, Henderson Reply Ex. 11; *see generally* U.S. Resp. To Defendants' Combined Statement of Additional Facts, ¶¶ 91.1 - 91.9.)

2. <u>The Meaning of AWP Is No Different for Generic Drugs</u>

Unhappy with the Court's plain meaning interpretation of AWP, defendants now argue that the Court was only referencing brand drugs, and not generic drugs, when it issued that ruling. Defendants go on to argue that HHS must have intended AWP to mean something different with respect to generic as opposed to brand drugs. Defendants are wrong on both counts.

CMS explicitly addressed the issue of AWP and generic drugs when amending its regulations in 1998 to cap Medicare payment for generics at 95% of the brand AWP, noting that:

> Our current regulations provide that, for multiple-source drugs, the AWP equals the median AWP of the generic forms of the drug. The AWP of the brand name products is ignored on the presumption the brand AWP is always higher than the generic AWPs. While this may have been true when the policy was first promulgated, it is not always true now. Therefore, the AWP for multiple-source drugs would equal the lower of the median price of the generic AWPs or the lowest brand name AWP.

63 Fed. Reg. 58,814, 58,849 (Nov. 2, 1998). In sum, the agency was aware of the issue raised by defendants now and did not believe the term "AWP" meant something different for generics.[4]

B. There Was No Government Policy to Approve False AWPS in Order to Cross-Subsidize Dispensing Fees

After dodging the issue in their initial briefs, defendants finally concede that they must show more than mere government knowledge to escape liability. Defendants' Combined Memorandum in Opposition at 21-22. They have not, however, produced anything approaching the type of evidence necessary to show government approval, *i.e.*, specific, contemporaneous communications from either state or federal government employees to defendants themselves. Defendants concede there was no direct communication by any federal or state official to them approving of their price reporting practices. Instead, defendants argue there was some kind of blanket "acquiescence" by federal and state governments for drug manufacturers to report any

[4]The Court explicitly applied its plain meaning interpretation of AWP to generic drugs in the class action litigation, when it held Bristol-Myers Squibb liable for reporting false AWPs for Rubex, which the Court described as a multi-source drug for the entire period at issue. *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20, 108 (D. Mass. 2007). The Court found that spreads were consistently above 30% for at least two of the six NDCs, with the highest spreads ranging from 55% to 438%. Based on these "large and consistent" spreads, the Court found liability for Rubex. *Id*. There is no question the Court was familiar with generic drugs when it applied its plain meaning interpretation of AWP.

amount as their AWP, and that a jury could conclude the government "embraced" false price reporting. *Id.* at 22. Defendants make this leap by arguing that federal and state governments interpreted their own regulations as permitting reporting of inflated AWPs, regardless of drug, in order to make up for supposed shortfalls in dispensing fees. Defendants then argue that federal and state government employees implemented their regulations in that fashion and approved defendants' false price reports and the resultant claims for reimbursement.

As noted above, the *Lachman* court made clear that agency interpretations of its own regulations must be formal and public. As Ms. Buto testified, "The government doesn't usually take steps unless it's through a regulation or a manual instruction or that kind of thing." (9/12/07 Buto Dep. at 105:13-16, Henderson Reply Ex. 21.) Lacking evidence of any formal approval of their conduct, defendants point to testimony by former federal or state employees as establishing that approval policy. Defendants also point to internal memos where government employees acknowledge their growing recognition that reported AWPs were unreliable and that dispensing fees were low. None of that translates into the approval required by the case law under the FCA.

Defendants also ignore testimony of current and former federal and state employees demonstrating that defendants' conduct was never approved. When asked about the meaning of estimated acquisition cost in the Medicaid regulations and cross-subsidization, Ms. Buto testified that "estimated acquisition cost was meant to cover certain costs and that the methodology ought to be accurate to the best of the state's ability and that's what we were trying to get at. These other costs for dispensing fees or other costs of the pharmacy or provider were not meant to be included." (9/12/07 Buto Dep. at 137:18-138:2, Henderson Reply Ex. 21.) When asked what costs were supposed to be covered by EAC, she answered: "Acquiring the drug. 'The price

generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of the drug most frequently purchased by providers.'" (9/12/07 Buto Dep. at 138:8-12, Henderson Reply Ex. 21.) Later in the deposition, defendants again sought to obtain testimony from Ms. Buto acknowledging some internal approval of cross-subsidization in both the Medicare and Medicaid programs. She made clear there wasn't any:

> I came at it then from the standpoint of this is drug payment. It's supposed to be paying a fair rate. That has been shown or we believe it to be the case that it's overpaying for the drug. We should do something about that. This issue of what it was covering or compensating for, to me that's a separate issue that really needs to be taken on directly. *If we should be covering these services we should be covering these services and we should do it in a straight-up way and it shouldn't be under some other mechanism.*

(9/12/07 Buto Dep. 205:15-206:5, Henderson Reply Ex. 21, emphasis supplied.) Ms. Buto would have known about and had responsibility for implementing any agency policy of cross-subsidization; there was no such policy.

Testimony of states by Rule 30(b)(6) witnesses also directly controverts defendants' claim of a uniform internal view regarding cross-subsidization. For example, when asked point blank whether Illinois ever had a policy or practice of paying increased ingredient costs in order to make up for some type of inadequate dispensing fee, the Rule 30(b)(6) representative for Illinois testified "No." (11/18/08 Parker Dep. 61:18-22, Henderson Reply Ex. 33.) Likewise, the Rule 30(b)(6) witness for Arkansas testified that Arkansas Medicaid did not have or execute any such policy. (12/10/08 Bridges Dep. 68:12-15, Henderson Reply Ex. 31.) California, the largest Medicaid program in the nation, did not have any such policy, and the Rule 30(b)(6) witness for California explained the folly of such a policy, when he testified that it would not be reasonable

to give manufacturers the power to decide when and how much to increase reimbursement to make up for alleged inadequacies in dispensing fees because "[t]he management of the --the program is -- with the State of California and with -- and the federal government, and to allow a -- what is considered in California a provider type, which a manufacturer is, to set rates for providers would -- would not make sense." (12/3/08 Gorospe Dep. 295:12-18, Henderson Reply Ex. 32.) Notwithstanding that the Maryland Medicaid agency understood from a survey that Maryland might be "underpaying" for the cost of filling a prescription, the state still "looked at it separately" from reimbursement for the estimated acquisition cost for the drug: "But we didn't set up a policy, well, because we're higher here and lower here it's okay. We looked at each one individually. And that's the best way I can answer that to you. It wasn't our policy to combine them both and say we're okay." (12/9/08 Fine Dep. 106:2-3, 10-14, Henderson Reply Ex. 46.)

II. FERA APPLIES TO THE UNITED STATES' UNJUST ENRICHMENT CLAIMS

Defendants' combined brief seeks to frame this issue as a government attempt to use the Fraud Enforcement and Recovery Act of 2009 (FERA) to "revive" expired claims after a pre-existing period of limitations has run. That is not the issue before this Court. The unjust enrichment claims never "expired," because the government's pleading always related back to the filing of relator's original complaint.

In the FERA provision at issue, Congress clarified its intent *ab initio* that all the government's pleadings relate back to the filing of relator's complaint where the claims arise out of the same conduct, transactions or occurrences as relator's complaint.[5] Pub. L. No. 111-

[5] Defendants do not argue that the Government's claims do not arise out of the same conduct, transactions or occurrences as relator's complaint; indeed, they could not because the claims for unjust enrichment are merely an alternate theory of liability based upon the exact same conduct, transactions and occurrences alleged in relator's initial complaint.

21(4)(b). This Court must take Congress at its word and treat this amendment as a clarification, not a substantive change in the law on relation back of government claims in *qui tam* matters. *See Red Lion Broad. Co. v. F.C.C.*, 395 U.S. 367, 380-81 (1969) ("Subsequent legislation declaring the intent of an earlier statute is entitled to great weight in statutory construction.") (footnote omitted); *Liquilux Gas Corp. v. Martin Gas Sales*, 979 F.2d 887, 890 (1st Cir. 1992) (following Puerto Rican legislature's explicit statement that subsequent legislation was clarifying). Because this amendment was a clarification and not a change in substantive law, its immediate effect raises no concerns about retroactive application. *See Piamba Cortes v. American Airlines, Inc.*, 177 F.3d 1272, 1283 (11th Cir. 1999) ("[C]oncerns about retroactive application are not implicated when an amendment that takes effect after the initiation of a lawsuit is deemed to clarify relevant law rather than effect a substantive change in the law.") (internal citations omitted).[6]

Defendants also argue that the first sentence of section 4(f)(2) of FERA,[7] applying certain enumerated sections of FERA to cases pending on the date of enactment, applies not to

[6]Cases cited by defendants are not contrary to the government's position; they speak neither to clarifying amendments in general nor to relation back of the government's common law claims under the FCA after FERA. For example, this court's decision in the matter of *Quaak v. Dexia, S.A.*, dealt with Sarbanes Oxley's enlargement of the limitations period for claims accruing under section 10 of the Securities and Exchange Act of 1934. 357 F. Supp. 2d 330 (D. Mass. 2005). In that case, there was no disagreement that plaintiffs' section 10 claims had accrued and expired under the then-existing limitations period before passage of the Sarbanes-Oxley bill. *Id.* at 334. After passage of Sarbanes-Oxley, plaintiffs had sought to revive the expired claims by arguing that the new, longer limitations period of Sarbanes-Oxley applied and revived the expired claims. *Id.* at 336-337. In the instant case, however, the government's claims for unjust enrichment never expired because Congress always intended for all the government's claims arising out of the same conduct, transactions or occurrences to relate back to the relator's complaint; the other cases cited by defendants are similarly distinguishable.

[7] Section 4(f) of FERA reads, "EFFECTIVE DATE AND APPLICATION.—The amendments made by this section shall take effect on the date of enactment of the Act and shall apply to conduct on or after the date of enactment, except that-- . . . (2) section 3731(b) of title 31, as amended by subsection (b) . . . shall apply to cases pending on the date of enactment."

the language clarifying relation back but to other of FERA's amendments to section 3731(b). Defs. Combined Br. at 44. That is not possible because, other than the renumbering of its subparts, the *only* amendment to section 3731(b) was the language clarifying relation back of the government's claims. Therefore, the only amendment to which the first sentence of FERA section 4(f)(2) could apply is the language clarifying relation back. Finally, since the enactment of FERA, the only court that appears to have ruled on this question held that the common law claim of unjust enrichment does relate back to the filing of relator's complaint. *United States ex rel. Bunk v. Birkart Globistics GmbH & Co.*, Nos. 1:02cv1168 & 1:07cv1198 at 3 (E.D.V.A., July 20, 2009) (attached). This Court should do the same.

III. DEFENDANTS ARE NOT ENTITLED TO SUMMARY JUDGMENT ON DAMAGES

A. The Defendants Are Responsible For Causing Damages Whenever Inflated Prices Resulted in Higher Reimbursement

Defendants continue to argue that they are not liable if payment for a drug was based on any price other than a published compendia price or on a formula that did not exactly match the state's reimbursement methodology. Defendants' Combined Response/Reply Memorandum, Master Docket ("MD") #6429, at 38-40, 42; *see also* Abbott's Summary Judgment Memorandum, MD #6186, at 11-20. They fail, however, to refute the direct connection between their inflated prices and the resulting reimbursement, and ignore the evidence put forth by the United States on this point.

The United States' position is straightforward. If a state's reimbursement methodology relied upon an inflated price which thereby triggered the selection of a higher reimbursement amount than otherwise would have been selected, then the defendants have caused the resulting

additional reimbursement. The use of the inflated prices in the reimbursement algorithm is the trigger that catapults the reimbursement upward. That reimbursement did not reach what might otherwise have been its apex because of honest efforts by the government to minimize the impact of defendants' fraud using MACs and FULs, does not break that initial causal link.[8] *See Massachusetts v. Mylan Labs*, 608 F. Supp. 2d 127, 147 (D. Mass. 2008) (explaining why providers' entry of inflated "usual and customary" charges did not insulate defendants from liability because of state's "lower of" methodology).[9]

Defendants offer no evidentiary support for their position; they simply ignore the plain terms of all state Medicaid programs' reimbursement regulations. An actual check of the data reveals the defendants' allegations to be false. *See* examples of claims paid based on Abbott's voluntarily lowered 2001 AWP, which was lower than the applicable MAC and billed charge, in Dr. Mark Duggan's September 21, 2009, Reply Affidavit, Henderson Reply Ex. 90, ¶¶12-13. Moreover, a chart prepared by Abbott's own expert shows that no claims were paid in amounts above Abbott's drastically lowered 2001 prices, and that payments based on other prices that existed before the Abbott price drop virtually disappear thereafter. See, infra, at 19-20.

---

[8] Currently, all but one of the Covered States reimburses pharmacy providers for prescription drugs under a "lower of" methodology in which payment is made based, at least in part, on the lower of (1) the state's EAC plus a dispensing fee, (2) the pharmacy's usual and customary charge (U&C) (sometimes referred to as the "billed amount"), or (c) the FUL. (US-Common-SOF ¶ 29). With limited exception, this "lower of" methodology was followed by all Covered States for the entire period, 1991 to the present. *Id.*, ¶ 25).

[9] In *Mylan Labs.*, this Court stated that "if the true U & C were lower than a true WAC, the defendants would only be liable for the amount of reimbursement in excess of the true WAC." As to MACs and FULs, we are faced with the flip side of that situation. Defendants do not allege, however, and there is no evidence to suggest, that the MACs and the FULs resulted in reimbursement *exceeding* the defendants' inflated AWPs. Thus, no limit to the damages is necessary (in part, because the limit is automatically built in -- the United States calculated damages based on the capped amount paid thanks to the applicable MACs and FULs, and not on the full amount of the inflated prices, clearly to the benefit of the defendants.) The defendants' attempt to convert this situation into a complete defense is unavailing. 608 F. Supp. 2d at 147.

The unusual situation where a state's use of a methodology that did not exactly match the stated reimbursement formula does not affect this causal link if the state still relied on the inflated prices. *See* United States' Memorandum of Law in Support of Motion for Partial Summary Judgment Against Abbott, MD #6319 at 27-29. It is undisputed that every state relied upon the inflated prices because the evidence shows that every state used FDB or Medispan prices. There is abundant evidence that the defendants (1) did not familiarize themselves with the legal requirements, standards and procedures of the Medicaid programs, (2) reported inflated prices in order to inflate Medicaid reimbursement for their customers, and (3) knew that the published prices were a key component of the reimbursement algorithm. Thus, the inference is fully supported that defendants are answerable for the outcome of their inflated prices even if they lacked knowledge of the precise manner in which it occurred.

Defendants also wrongly contend that the United States has provided no evidence that (1) Dr. Duggan's difference calculation is based on what Medicaid would have reimbursed; and (2) the Medicare carriers would in fact choose to include Dr. Duggan's prices in their arrays.[10] Defendants are wrong on both counts.

Although the United States is not obligated to prove in opposition to defendants' motion that the revised prices would have been used, there is abundant evidence that would have been the case. The United States *and the defendants* both have presented evidence that the Medicare and Medicaid programs generally relied upon the prices published by Red Book or First

[10] Defendants' Combined Response/Reply Memorandum, MD #6429, at 36 ("no evidence here that such Medicaid programs used any of the Defendants' AWPs[,]"), and 40 ("DOJ provides no evidence that any state (let alone all of them) would have paid less even for claims based on MACs, FULs, and U&Cs had different compendia prices been reported") and Defs. Response to US-Common-SOF , MD #6439, ¶¶ 128,132 and 133.

Databank.[11] There is also no material dispute that the defendants controlled what was published by Red Book or First Databank.[12] Abbott's own expert presented a chart which demonstrates that payments would have been based on lower reported prices. Specifically, Figure 4 of the Expert Report of Steven J. Young, March 6, 2009, page 17 (Abbott Summary Judgment Ex. EO, MD #6211), showed that the large majority of Kentucky claims for sodium chloride were reimbursed in an amount equal to Abbott's annually increased AWP from 1996 through early 2001, and that when Abbott reported lower prices in mid-2001, the reimbursement automatically followed suit, using prices that were drastically lower than the prices Abbott had previously caused to be published.[13]

The defendants also press a speculative (and irrelevant) theory that states would have revised their reimbursement methodologies as a result of a price decrease by increasing other payments for dispensing fees and professional services. But summary judgment against the United States is wholly inappropriate on such a basis. Moreover, the defendants present no evidence suggesting that the determination of ingredient cost by reference to the compendia would have been changed if defendants stopped reporting inflated prices. Mr. Young's chart demonstrates that low AWP's combined with a "lower of" methodology results in the

[11] *See* US-Common-SOF, MD #6316, ¶ 34, and Henderson Common Ex. 24 (Knerr Decl., ¶ 24c); Defs. Combined L.R. 56.1 Statement of Additional Material Facts, MD #6447, ¶ 37(a) to 37(aa), and ¶ 104(a) to 104(k).

[12] *See, e.g.*, United States Exhibit 1 in Support of Summary Judgment as to Abbott, MD #6302, Declaration of Patrick Ormond, ¶¶ 11 and 12, and Appendices B5, B6 and B7; US-Dey-SOF, MD #6296, ¶¶ 58-71; and US-Rox-SOF, MD #6293, ¶¶ 18-25, which establish that Dey and Roxane directly reported both WACs and AWP to the compendia.

[13] US-Abbott, Ex. 1, Declaration of Pat Ormond, Appendix B-1, p. 3 and B-3, pp. 2-3, shows the Abbott catalog prices for the 10-ml sodium chloride product steadily increasing from $1.32, to $1.39, to $1.46, to $1.53, to $1.61, and then dropping to $ .40 in 2001, with the corresponding changes to Abbott's FDB AWPs.

elimination of payments based on any alternative amount higher than the AWP. *See also,* Henderson Reply Ex. 90 (Duggan Decl. at ¶¶ 12-13), and Ex. 91 (Decl. of Suzanne Graydon).

Turning to Medicare, there is substantial evidence that the Medicare carriers would have included Dr. Duggan's prices in their arrays, including that all carriers were hired by CMS to perform the same job, received the same instructions, and used the same price source – Red Book. For those arrays Dr. Duggan did use in his analysis, one of defendants' products was included in almost every case. United States' Local Rule 56.1 Statement of Undisputed Material Facts Common to All Defendants, ¶¶ 158-159 and Henderson Common Ex. 41 (Duggan Decl.), ¶¶ 92-94. The Declaration of Carolyn Helton, at ¶¶ 32-40 provides direct evidence on this point. *See also* 3/13/2008 CIGNA (Helton) dep. at 295:14- 298:22, Henderson Reply Ex. 98.

Thus, if the defendants had caused more accurate prices to be published by Red Book or First Databank, those prices would necessarily have been used by the Medicare and Medicaid programs, and those more accurate, but lower AWPs would have trumped any higher alternative prices as a result of the application of the "lower of" methodology. The defendants' invitation to embark upon some speculative analysis about whether the federal government or the states would have changed the system to use the lower prices turns the issue on its head. Both were already using a system that would have used the lower prices and the defendants have introduced no evidence to suggest otherwise.

B. The Extrapolations Used by the Government Are Reliable

Summary judgment on damages is not appropriate because one party asserts that extrapolated damage figures "likely" overstate the alleged damages. Defs.' Common Memo of Law (MD #6429), at 41. Defendants must instead show that there are no facts to support the

inference that Dr. Duggan's calculations are reliable. Defendants have not satisfied this burden.[14]

Defendants purport to introduce some additional factual support pertaining to damages in their Combined L.R. 56.1 Statement of Additional Facts (MD #6447), but those materials are not appropriately used to support the defendants' affirmative motions. Nonetheless, the United States will briefly address them.

Defendants rely heavily on a new declaration submitted by one of Dey's experts to attack the Medicaid damages. *See* Bradford 8/28/09 Declaration, MD #6426-121, Defs. Ex. 405. However, that declaration is flawed as shown by the United States' Expert Dr. Mark Duggan. *See* September 21, 2009, Declaration of Mark Duggan, Ph.D., Henderson Reply Ex. 90. Among other things, Dr. Bradford calculates and compares the average amount paid *per claim*, not the average amount paid *per unit*, and thus fails to account for differences in the number of units on the typical claim in each state, (*e.g.*, 219 in New York versus 109 in Pennsylvania). *Id.* at ¶¶ 3-4. Dr. Bradford then misquotes Dr. Duggan to set the stage for contradicting him, but still ends up affirming his conclusions regarding the *general* stability of the ratio of damages from state to state. *Id*. at ¶¶ 5-7. Dr. Bradford attempts to show that using the data collected directly from the states, rather than extrapolating, would result in a significant difference in the damages, but he only manages to show, at best, that Medicaid damages for Dey would be reduced from approximately $160 million to $154.4 million, a drop of $4.6 million or 3.5%.[15] Yet Dr. Bradford's analysis is flawed because he failed to properly apply Dr. Duggan's methodology and

[14] The United States will be providing further opposition to this issue in its response to Abbott's Motion in Limine on October 19, 2009.

[15] The defendants point to a claimed 20% difference in the damages for the extrapolated states in order to further dramatize the modest difference.

used incomplete state data. *Id*. at ¶¶ 8-11. At best, Dr. Bradford's declaration creates a dispute between experts that is best resolved by a jury.

Defendants' attack on the calculation of Medicare damages fares no better. The defendants fail to counter the well supported factual support and related inferences that all of the Medicare carriers would have used the defendants' prices in their pricing arrays. The discussion, *supra* at 16-17, provides ample factual support that the Medicare arrays were prepared using the Redbook AWPs of the defendants, and the alternative AWPs of the United States' expert would have been similarly used. As noted, all carriers were utilizing the same procedures and the defendants' inflated AWPs were routinely relied upon. For those arrays Dr. Duggan did use in his analysis, one or more of defendants' products was included in almost every case. With respect to the additional calculations performed as to Abbott, the Medicare allowed amount is equal to the unique published price of an Abbott product over 1.3 million times, demonstrating that an Abbott AWP was used. US-Common-SOF, MD #6316, ¶¶ 158-159 and Henderson Common Ex. 41 (Duggan Decl.), ¶¶ 92-94.

In sum, defendants have fallen far short of demonstrating any entitlement to summary judgment on damages related issues. They have done nothing more than show that their experts would have calculated a different figure. They have not shown that the detailed review of millions of claims performed by Dr. Duggan was unreliable.

CONCLUSION

For the reasons set forth above and in the plaintiffs' defendant-specific summary judgment briefs, plaintiffs respectfully request that the Court deny defendants' motions for summary judgment and grant plaintiffs' motions for partial summary judgment.

Respectfully submitted,

For the United States of America,

MICHAEL K. LOUCKS
ACTING UNITED STATES ATTORNEY

/s/ George B. Henderson, II
George B. Henderson, II
Barbara Healy Smith
James J. Fauci
Assistant U.S. Attorneys
United States Courthouse
Suite 9200, 1 Courthouse Way
Boston, MA 02210
Phone: (617) 748-3272
Fax: (617) 748-3971

JEFFREY H. SLOMAN
ACTING UNITED STATES ATTORNEY
SOUTHERN DISTRICT OF FLORIDA

Mark A. Lavine
Ann St. Peter-Griffith
Special Assistant U.S. Attorneys
99 N.E. 4th Street, 3rd Floor
Miami, FL 33132
Phone: (305) 961-9003
Fax: (305) 536-4101

Dated: Sept. 22, 2009

TONY WEST
ASSISTANT ATTORNEY GENERAL

/s/ Laurie A. Oberembt
Joyce R. Branda
Daniel R. Anderson
Renee Brooker
Justin Draycott
Rebecca Ford
Andy Mao
Laurie A. Oberembt
Elizabeth Strawn
Civil Division
Commercial Litigation Branch
P. O. Box 261
Ben Franklin Station
Washington, D.C. 20044
Phone: (202) 514-3345
Fax: (202) 307-3852

For the relator, Ven-A-Care of the Florida Keys, Inc.,
JAMES J. BREEN
The Breen Law Firm, P.A.
Suite 260
5755 North Point Parkway
Alpharetta, Georgia 30022
Phone (770) 740-0008

SUSAN S. THOMAS
GARY L. AZORSKY
ROSLYN G. POLLACK
Berger & Montague, P.C.
1622 Locust Street
Philadelphia, PA 19103
Telephone: 215-875-3000

CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above "COMMON REPLY MEMORANDUM OF LAW IN SUPPORT OF CROSS-MOTIONS FOR PARTIAL SUMMARY JUDGMENT AND SUR-REPLY IN OPPOSITION TO THE DEFENDANTS' MOTIONS FOR SUMMARY JUDGMENT" to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Laurie A. Oberembt
LAURIE A. OBEREMBT
Senior Trial Attorney

Dated: Sept. 22, 2009